8EHQ-1093-12717

COMPANY SANITIZED

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93 OCT -5 PM 12:00

October 4, 1993

Document Processing Center (TS-790)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Attention: **SECTION 8(E) COORDINATOR**

Dear Sir/Madam:

The purpose of this letter is to inform you under Section 8(e) of TSCA of the preliminary results of an acute inhalation (rat) 4-hour LC50 study on the chemical N-(2,3-Dimethylphenyl)maleimide [CAS 31581-09-6].

The test material was administered, as a dust, to ten (5/sex) rats at a mean concentration of 1400 mg/M3. All ten animals were dead within 2 hours of exposure. Ten (5/sex) rats were then exposed to a mean concentration of 100 mg/M3. Two animals died during exposure; 8/10 were dead by Day 1 and 9/10 were dead by Day 2. One female is presently alive and doing well. A third group of ten (5/sex) rats were dosed at a mean concentration of 13 mg/M3. No deaths were reported immediately following exposure. We will continue to monitor the exposed animals through a 14-day observation period. The study will continue with further exposure levels in order to accurately calculate a four-hour LC50.

A copy of the full report will be submitted as soon as it is received.

Further questions regarding this submission may be directed to at the address above or .

Sincerely,

mm

10-22-93

5 pgs.

SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS

8(e) Submission on N-(2,3-Dimethylphenyl)maleimide

Substantiation Questions

1. **Is your company asserting this confidential business information (CBI claim on its own behalf? If the answer is no, please provide company, name, address and telephone number of entity asserting claim.**

   Confidentiality claim is made on behalf of

2. **For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.**

   Confidentiality is requested for a period of three years (until 1996). This time period is requested to complete R&D, product evaluation, pilot production and to develop business plans and customer base.

3. **Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.**

   No.

4. **Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.**

   The information has been given only to those with the need-to-know. Information has appeared only in Company documents which have limited circulation and which are considered Confidential information. All employees must sign an agreement which binds them from disclosing Confidential information when they leave. The need for confidentiality has been reemphasized to employees working on the research project.

5. **If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).**

Information claimed as confidential has only been released to those with a need-to-know.

6. **Does the information claimed as confidential appear or is it referred to in any of the following:**

   a. **Advertising or promotional material for the chemical substance or the resulting end product;**

   b. **Material Safety Data Sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);**

   c. **Professional or trade publications; or**

   d. **Any other media or publications available to the public or to your competitors.**

If answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

None of the information which is claimed as confidential has been disclosed in any public document.

7. **Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.**

No.

8. **Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the casual relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors' access to your customers. Address each piece of information claimed CBI separately.**

Material appears to have several desirable physical properties. Competition could produce/sell this material thereby jeopardizing our commercial position. We will be spending substantial amounts of upfront money on R&D, pilot/manufacturing and business-related efforts.

- Potential sales are in the many millions of dollars/yr.
- End use and process patents have not been filed as yet.

9. **Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?**

No. We expect to file process and possibly end use patent.

10. **Is this substance/product commercially available and if so, for how long has it been on the commercial market?**

a. **If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?**

Not applicable.

b. **If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.**

Product is not commercially available. The product is presently in Discovery Research. If a market is established, it would take 2-3 years.

c. **What is the substance used for and what type product(s) does it appear in?**

11. **Describe whether a competitor could employ reverse engineering to identically recreate the substance?**

Yes, it would be very easy to identify by standard analytical methods.

12. **Do you assert that disclosure of this information you are claiming CBI would reveal:**

a. **Confidential processes used in manufacturing the substance;** Yes

b. **If a mixture, the actual portions of the substance in the mixture;** or Not Applicable.

c. **Information unrelated to the effects of the substance on human health or the environment?** Yes.

If your answer to any of the above questions is yes, explain how such information would be revealed.

Knowledge of chemical structure will reveal manufacturing process - There is only one method to make it. In addition, CBI information would reveal chemical identity associated with and therefore, its end-use application would be obvious to those familiar with this class of materials.

13. **Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.**

CAS# 031581-09-6

14. **Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.**

No.

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1093-12717 (3) SEQ A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Confidential

SUB. DATE: 10/04/93 OTS DATE: 10/05/93 CSRAD DATE: 10/22/93

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME: Maleimide, N-(2,3-Dimethylphenyl)

CAS# 31581-09-6

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	(01) 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
021?	HUMAN EXPOS (PROD CONTAM)	01 02 04
021	HUMAN EXPOS (ACCIDENTAL)	01 02 04
02	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
02	METAB/PHARMACO (ANIMAL)	01 02 04
02	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
(0248)	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY
YES (CONTINUE)
NO (DROP)
(DETERMINE)

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER:

SPECIES: RAT

TOXICOLOGICAL CONCERN:
LOW
MED
HIGH

USE: R&D

PRODUCTION:

COMMENTS: Non-Cap